



## UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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18N2/0607

GENENTECH, INC.
GINGER R. DREGER
460 POINT SAN BRUNO BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

☐ Note attached communication from the Examiner
☐ This paties is issued in view of applicants communication.

# NOTICE OF ALLOWANCE AND ISSUE FEE DUE

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TITLE OF

INVENTIONARIANTS OF TISSUE PLASMINOGEN ACTIVATOR, COMPOSITIONS AND METHODS OF USE FOR SAME (AS AMENDED)

		ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
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THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

#### HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY Status shown above.
  - If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
  - A. If the Status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
  - B. If the Status is the same, pay the FEE DUE shown above.
- If the SMALL ENTITY is shown as NO:
- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by a charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.
- III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees.



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TRANSMIT THIS FORM WITH PART B WHEN AUTHORIZING USE OF A DEPOSIT ACCOUNT PTOL-85C (REV 12-88)(OMB Cloarance is pending)

#### PART B - ISSUE FEE TRANSMITTAL

MAILING INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE. Blocks 2 through 6 should be completed where appropriate. All further correspondence including the Issue Fee Receipt, the Patent, advanced orders and notification of maintenance fees will be mailed to addressee entered in Block 1 unless you direct otherwise, by: (a) specifying a new correspondence address in Block 3 below; or (b) providing the PTO with a separate

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			Not used	Street Address			
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06/07/94

DATE MAILED:

NOTICE	OF ALLOWABILITY	
PART I.	to to to to to	
1. A This communication is responsive to <u>amendmen</u>	T. filed 3/14/94	
2. All the claims being allowable, PROSECUTION ON THe herewith (or previously mailed), a Notice Of Allowance	NE MERITS IS (OR REMAINS) CLOSED in this application. If not included And Issue Fee Due or other appropriate communication will be sent in due	
3. 7 The allowed claims are 1.11-12.16-17. 24-28	? 30-31 58-10, 62 -63, 67-73 which how bean someter	o.
4. The drawings filed on	are acceptable. a. 1- 3 8 11-14 18 17 19 20 24 21 25 03 24	j
5. Acknowledgment is made of the claim for priority und received. [] been filed in parent application Serial No	2, 30-31, 58-60, 62-65, 67-73 which, have like a senumber are acceptable. as 1-8, 11-16, 18, 17, 19, 20, 24, 21, 25, 23, 25, 26, 35 U.S.C. 119. The certified copy has [_] been received. [_] not been superting	يُو
6. M Note the attached Examiner's Amendment.	, and the second se	0
7. Mote the attached Examiner Interview Summary Record.	PTOL-413.	
8. M Note the attached Examiner's Statement of Reasons for A	Allowance.	
9.   Note the attached NOTICE OF REFERENCES CITED, PTG	<b>D-892</b> .	
10. Mote the attached INFORMATION DISCLOSURE CITATION	)N, PTO-1449.	
PART II.	·	
A SHORTENED STATUTORY PERIOD FOR RESPONSE to com	nply with the requirements noted below is set to EXPIRE THREE MONTHS to timely comply will result in the ABANDONMENT of this application. FR 1.136(a).	
Note the attached EXAMINER'S AMENDMENT or NOTIFICATION OF declaration is deficient. A SUBSTITUTE OATH OR DECI	CE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath LARATION IS REQUIRED.	
APPLICANT MUST MAKE THE DRAWING CHANGES IN OF THIS PAPER.	DICATED BELOW IN THE MANNER SET FORTH ON THE REVERSE SIDE	
a. Drawing informalities are indicated on the NOTICE	E RE PATENT DRAWINGS, PTO-948, attached hereto or to Paper No.	
<ul> <li>The proposed drawing correction filed on</li></ul>	has been approved by the examiner. CORRECTION IS	
<ul> <li>c. Approved drawing corrections are described by the REQUIRED.</li> </ul>	examiner in the attached EXAMINER'S AMENDMENT. CORRECTION IS	
d. Formal drawings are now REQUIRED.		
Any response to this letter should include in the upper right I AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF THE N	hand corner, the following information from the NOTICE OF ALLOWANCE ROTICE OF ALLOWANCE, AND SERIAL NUMBER.	
Attachments:		
Examiner's Amendment	_ Notice of Informal Application, PTO-152	
Examiner Interview Summary Record, PTOL- 413	Notice re Patent Drawings, PTO-948	
✓Reasons for Allowance  Notice of References Cited, PTO-892	_ Listing of Bonded Draftsmen	
_ NOUGE OF REIERENCES CITED, PTO-092	_ Other	

Information Disclosure Citation, PTO-1449

-2-

Serial No. 08/035,427 Art Unit 1812

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An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

Amend claim 28 as follows.

(Twice amended) The variant of claim 16 that is rendered resistant to enzymatic cleavage by an amino acid substitution at position 275 or [the] 277 [site] or both.--

In claim 31, line 24, please change "N103A296A297AA298A299 t-PA to --N103A296A297A298A299 t-PA--. This corrects a clear typographical error.

Amend claim 70 as follows.

--76. (Amended) A composition for treating a vascular disease or condition comprising a therapeutically effective amount of t-PA variant of claim for in admixture with a pharmaceutically acceptable carrier.--

(Amend claim 71 as follows.)

-- (Amended) A composition for treating a vascular disease or condition comprising a therapeutically effective amount of t-PA variant of claim at in admixture with a pharmaceutically acceptable carrier. --

Authorization for this Examiner's Amendment was given in a telephone interview with Dr. Ginger Dreger on 23 May 1994.

The following is an Examiner's Statement of Reasons for Allowance:

Claim 15 has been canceled. Claims 1, 11-12, 16-17, 24-28, 30-31, 58-60, 62-65, and 67-73 are under consideration by the Examiner.

Application 07/841,698 was filed on 2/26/92 and assigned to Genentech on the same date. Application 07/480,691 was filed on 2/15/90 and assigned to Genentech on 3/30/90. The instant application 08/035,427 is a continuation of application 07/824,740 which is a continuation of application 07/480,691. According to the provisions of MPEF 306 the instant application is thereby assigned to Genentech. Reel/frame 5277/0157 refers to the 07/480,691 application. This establishes that the conflicting

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inventions were commonly owned at the time the invention in this '698 application was made and precludes a rejection under 35 U.S.C.  $\S$  103 based upon the commonly assigned case as a reference under 35 U.S.C.  $\S$  102(f) or (g).

The provisional rejection of claim 59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-15 of co-pending application Serial No. 07/841,698 (now refiled as 08/168,060) has been withdrawn in accordance with MPEP 804.

The provisional rejection of claims 72 and 73 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 of co-pending application Serial No. 07/841,698 (now refiled as 08/168,060) in view of Larsen et al. (WO 87/04722) has been withdrawn in accordance with MPEP 804.

It is noted that claims 1-25 of application 08/168,060 have been canceled and replaced with claims 26-38. Claims 59, 72, and 73 of the instant application are drawn to methods of treatment comprising administering particular t-PA mutants. The claims of the co-pending application are drawn to methods of treatment comprising bolus administration of particular t-PA mutants. particular t-PA mutants administered are co-extensive. The claims of the instant application encompass the invention of the copending application as the claims of the instant application can be literally infringed without literally infringing the claims of the Applicant's arguments concerning the co-pending application. unexpected results for the co-pending application's claims are not persuasive. It is noted that the co-pending application does not compare the clearance time for bolus and continuous infusion of the mutants but only compares the clearance time for bolus and continuous infusion for wild-type t-PA. The recited mutations to t-PA are known to provide improved half-life and no unexpected property has been demonstrated. In addition, the results set forth in the co-pending application are not commensurate with the claims. However, as these provisional double patenting rejections are the only rejections remaining at issue in the instant application they are hereby withdrawn as set forth in MPEP 804. The instant claims may form the basis for an actual, rather than provisional, double patenting rejection in the co-pending application upon issuance of the patent.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-4227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is (703) 308-0666.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

GARNETTE D. DRAPER

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